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IS 3236 (1992): Hypodermic syringes for general purposes
[MHD 12: Hospital Equipment]

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(द्वासरा पुनरीक्षण)

Indian Standard

**HYPODERMIC SYRINGES FOR GENERAL
PURPOSES — SPECIFICATION**

(*Second Revision*)

UDC 6 15·473·3

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BUREAU OF INDIAN STANDARDS
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FOREWORD

This Indian Standard (Second Revision) was adopted by the Bureau of Indian Standards, after the draft finalized by the Medical Instruments and Disposables Sectional Committee, had been approved by the Medical Equipment and Hospital Planning Division Council.

This standard was first published in 1965 and revised in 1980. Its second revision has been taken up mainly to incorporate the provisions of Amendment No. 1 and Amendment No. 2 issued earlier and delete reference to IS 3234 (Part 2) : 1986 covered vide Amendment No. 2, since this standard is yet to be published.

The interchangeability between syringes and needles, and between barrels and pistons of the syringes is an important aspect where selective assembly becomes somewhat difficult due to the mass sterilization of instruments. Interchangeability between the needles and syringes is assured due to adoption of **Luer** type of fitting for the conical tip of the syringe and hub of the needle [see IS 3234 (Part 1) : 1986 Conical fittings with a 6% (LUER) taper for syringes, needles and other medical equipment: Part 1 General requirements (second **revision**)]. **The** barrels and the pistons are made interchangeable by manufacturing and testing them to a high degree of accuracy to the prescribed dimensions. The interchangeable all glass syringes are covered separately in IS 11400 : 1985 'Hypodermic syringes, interchangeable type for general purposes'.

In view of the fact that some manufacturers have already geared the production of barrels and pistons of all-glass syringes to dimensions which are different from those given in IS 11400 : 1985, but still they claim interchangeability within their own manufacture, such syringes shall be covered by the provisions of this standard (called **Type I** syringe, see 3.1). If the manufacturer uses BIS certification mark on such syringes, the **corresponding** identification number on the barrel and the piston may not be necessary and the identification mark of the firm alone on barrel and piston will be sufficient (see **also** 6.1).

Non-interchangeable hypodermic syringes (called **Type II** syringe, see 3.1) can also be made, if required, by selective assembly and fitting of barrels and pistons and having the same identification marking on them to facilitate their matching.

The interchangeability between the barrels and pistons of metal-and-glass syringes has been left to the individual manufacturer to achieve and maintain within own manufacture.

This standard covers the requirements for reusable type hypodermic syringes only, whereas the hypodermic syringes for single use are covered in IS 10258 : 1982 'Sterile hypodermic syringes for single use'.

For the purpose of deciding whether a particular requirement of this standard is complied with, the final value, observed or calculated, expressing the result of a test or analysis, shall be rounded off in accordance with IS 2 : 1960 'Rules for rounding off numerical values (**revised**)'. The number of significant places retained in the rounded off value should be the same as that of the specified value in this standard.

Indian Standard

HYPODERMIC SYRINGES FOR GENERAL PURPOSES — SPECIFICATION

(Second Revision)

1 SCOPE

1.1 This standard specifies requirements for general purpose hypodermic syringes for medical use.

2 REFERENCES

2.1 The following Indian Standards are necessary adjuncts to this standard:

IS No.	Title
3234 (Part 1) : 1986/ ISO 594/1: 1986	Conical fittings with a 6 percent (Luer) taper for syringes, needles and other medical equipment : Part 1 General requirements (second revision)
3235 : 1988/ ISO 595/2 : 1987	General requirements for syringes for medical use (second revision)

3 TYPES

3.1 The general purpose syringes shall be of two types :

Type I — Syringes which are interchangeable within one's own manufacture.

Type II — Non-interchangeable syringes.

4 SIZES AND DIMENSIONS

4.1 Typical all-glass and metal-and-glass syringes are shown in Fig. 1.

4.2 The capacities of syringes shall indicate their sizes, which shall be in accordance with Table 1.

4.3 The sub-divisions or scale intervals shall be in accordance with col 4 of Table 1. The sub-divisions other than those specified therein may also be permitted subject to agreement between the purchaser and the supplier.

4.4 The length of scale, the minimum length of the graduation and the numbering of the graduations shall be in accordance with Table 1.

4.5 Dimensions of all-glass syringes shall be in accordance with Table 2.

4.6 The dimensions of metal-and-glass syringes shall be in accordance with Table 3.

5 REQUIREMENTS

5.1 For general requirements, the provisions covered under IS 3235 : 1988/ISO 595/2 : 1987 shall apply, unless otherwise stated in this standard.

5.2 Nozzle

The male conical tip of the nozzle shall be of Luer type and shall comply with IS 3234 (Part 1) : 1986/ISO 594/1 : 1986.

5.2.1 When the metal-and-glass syringe is provided with a Luer lock connection, it shall be in accordance with Fig. 2.

5.2.2 If the metal parts are electroplated, the dimensions indicated in Fig. 2 shall be taken as dimensions after plating.

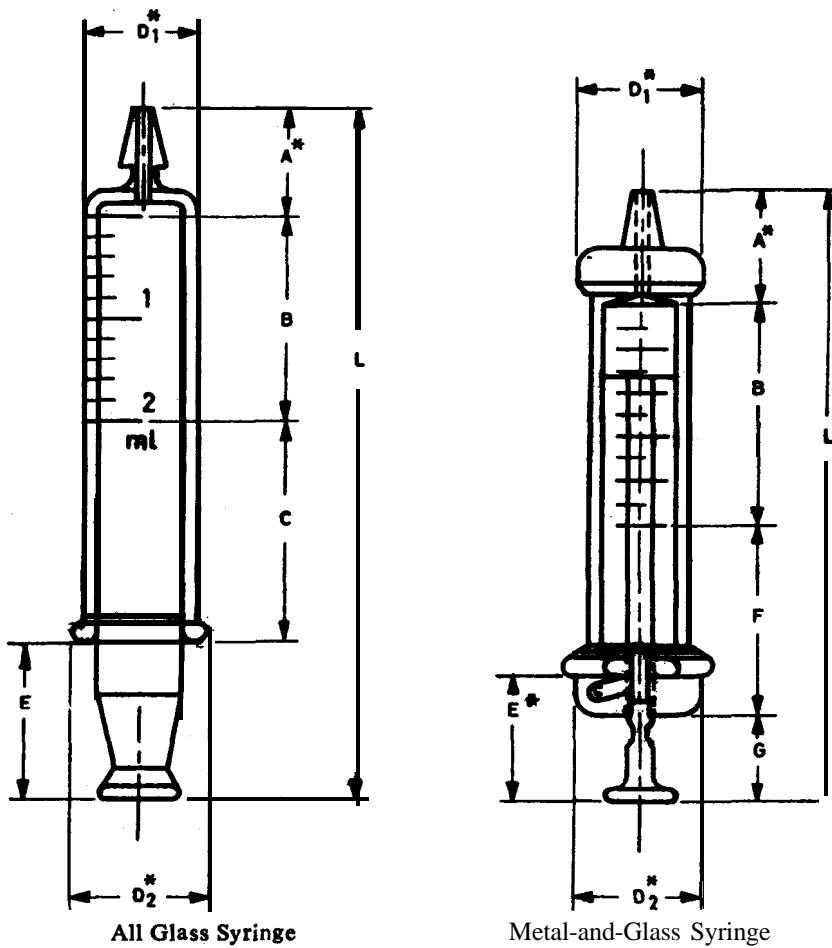
5.3 Numbering

The numbering of scale intervals shall be in accordance with col 6 of Table 1. The number shall be close to, but shall not touch the ends of the graduation mark to which it relates. The numbering shall generally conform to the details given in Fig. 3. The numbers shall be clearly defined, durable and easily legible.

5.4 The piston shall be easily visible through the barrel and the fiducial line shall be capable of being judged against the graduations very accurately.

5.5 A piston brake, if provided, shall be such that when the syringe is held in a vertical position with the nozzle upside, the piston shall remain stationary and shall not descend under its own weight. The braking action shall not be so severe as to interfere unduly with the manipulation of the piston.

5.6 The diameter of the effluent shall be in accordance with Tables 2 and 3. It shall be concentric with the tip.



NOTES

1 The above diagrams are mainly for the purpose of representing the dimensional characteristics defined, but the indication of shapes do not form a Part of the specification.

2 The dimensions followed by an asterik (*) for example A* are indicated, but they do not form a part of the specification.

FIG. 1 HYPODERMIC SYRINGES

Table 1 Range of Sizes, Graduated Scale and Tolerance on Graduated Capacity of Syringes
(Clauses 4.2, 4.3, 4.4 and 5.3)

Graduated Capacity of Syringe	Tolerances on Graduated Capacity and on Any Capacity Greater than Half the Graduated Capacity	Length of Scale B	Scale Interval	Minimum Length of Long Graduation Marks	Numbering of Scale Intervals
(1) ml	(2) percent	(3) mm	(4) ml	(5) mm	(6)
2	± 5	31 ± 4	0.2	6	1.2
5	± 4	41 ± 5	0.5	8	1, 2, 3, 4, 5
10	± 4	52 ± 6	1	10	5, 10
20	± 4	58 ± 6	1 or 2	13	10, 20
30	± 4	75 ± 8	1 or 2	13	10, 20, 30
50	± 4	88 ± 10	5	16	10, 20, 30, 40, 50
100	± 4	105 ± 10	5	20	20, 40, 60, 80, 100

NOTES

1 Short graduation shall be equal to half length of the long graduation.

2 Finer graduations are also permitted.

Table 2 Dimensions of All-Glass Syringes(*Clauses 4.5, 5.6, and Fig. 1*)

Graduated Capacity of Syringe	Length of Non-Graduated Part of the Barrel of Syringe	Minimum Length of Projection of Piston	Maximum Overall Length	Minimum Thickness of Glass	Diameter of Effluent
(1) ml	(2) mm	(3) mm	(4) mm	(5) mm	(6) mm
2	25 to 35	10	100	1.2	0.80 to 1.8
5	25 to 35	13	125	1.4	0.80 to 1.8
10	30 to 40	15	140	1.4	1.0 to 2.1
20	30 to 40	15	165	1.6	1.0 to 2.1
30	35 to 45	15	185	1.6	1.0 to 2.1
50	40 to 50	20	205	1.8	1.6 to 2.1
100	40 to 60	20	245	1.8	1.6 to 2.1

5.7 All-glass syringes shall have the tip ground to suit the hub of the needle. In metal-and-glass syringes, the metal tip shall be securely fixed and tip meant for the needle shall have the required taper to fit the hub of the needle.

5.8 The Luer lock type of the tip shall have a collar with an internal thread to receive the corresponding needle hub, which when rotated, shall securely hold it.

5.9 Type I syringes shall pass the interchangeability test given in 5.9.1.

5.9.1 Syringes shall be selected at random from various lots and their plungers and barrels completely separated. These parts shall be thoroughly wetted with distilled water. While in the moist condition, attempts shall be made to match plungers and barrels at random. All

plungers shall be capable of fitting into barrels and capable of moving freely up and down with out evidence of sticking, jumping, shake or play. Syringes thus assembled shall pass the leakage test specified in 5.4 of IS 3235 : 1988.

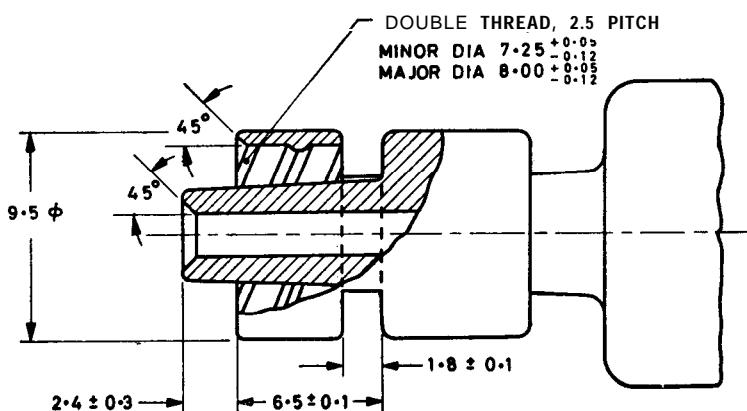
6 MARKING

6.1 Each syringe shall be legibly and durably marked as given in 6.1.1 and 6.1.2.

6.1.1 *Type Z Syringes*

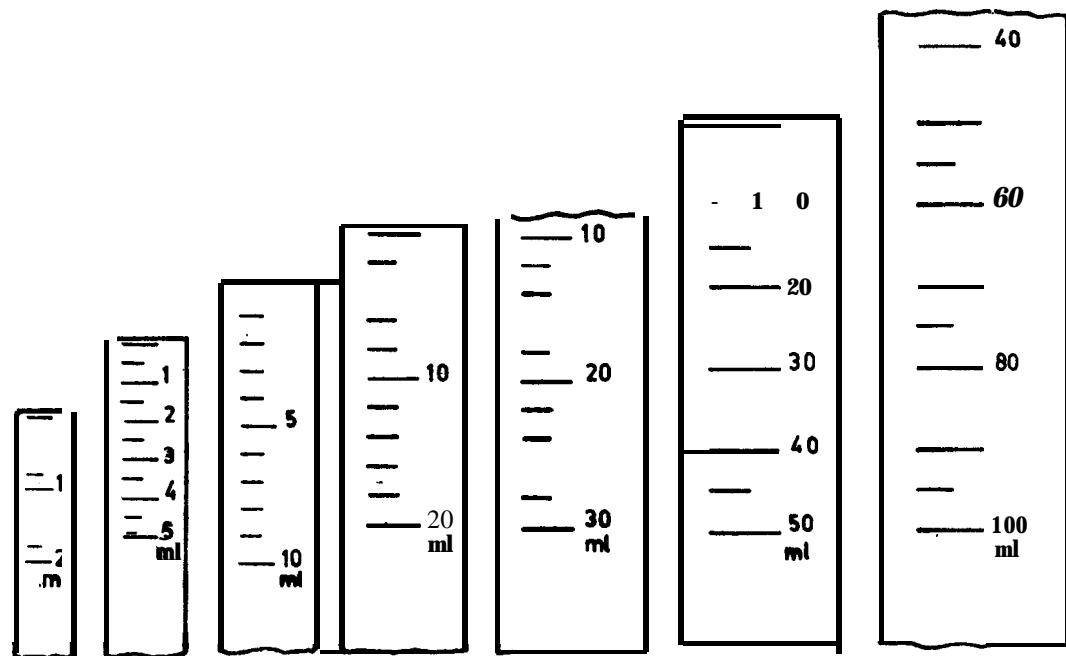
6.1.1.1 The barrel of the syringe shall be marked with the following:

- An indication of the source of manufacture; and
- Unit of capacity, ml.



All dimensions in millimetres.

FIG. 2 DETAILS OF LUER LOCK CONNECTIONS



NOTES

1 Both horizontal as well as vertical scale numbering are permitted.

2 Finer graduations are also permitted.

FIG. 3 GRADUATIONS ON HYPODERMIC SYRINGES

Table 3 Dimensions of Metal-and-Glass Syringes

(*Clauses 4.6 and 5.6, and Fig. 1*)

Graduated Capacity of syringes	Minimum Length of Non-graduated Part of Barrel of the Syringe <i>F</i>	Minimum Length of Projection of Piston <i>G</i>	Total Maximum Length <i>L</i>	Minimum Thickness of Glass	Diameter of Effluent
(1) ml	(2) mm	(3) mm	(4) mm	(5) mm	(6) mm
2	20	9.0	100	1.2	0.80 to 1.8
5	22	12.5	125	1.4	0.80 to 1.8
10	28	12.5	140	1.4	1.0 to 2.1
20	28	12.5	165	1.6	1.0 to 2.1
30	30	12.5	185	1.6	1.0 to 2.1
60	35	12.5	205	1.8	1.6 to 2.1
100	35	12.5	245	1.8	1.6 to 2.1

NOTE — The criterion used to determine dimensions *F* and *G* of metal-and-glass syringes differs from that used to determine dimensions *C* and *E* of all-glass syringes, since the thickness of the metal cap of metal-and-glass syringes is variable and is not specified in this standard. The purpose of dimensions *E* and *G* is to ensure that there is sufficient space around the piston head to facilitate manipulation.

6.1.1.2 The piston of the syringe shall be marked with an indication of the source of manufacture.

6.1.2 **Type ZZ Syringes**

6.1.2.1 The barrel of the syringe shall be marked with the following:

- a)** An indication of the source of manufacture;
- b)** Unit of capacity, ml; and

c) A suitable identification mark to facilitate its matching with the corresponding piston.

6.1.2.2 The piston of the syringe shall be marked with the same identification mark as provided in **6.1.2.1 (c)**.

7 **PACKING**

7.1 Each syringe shall be individually packed as agreed to between the manufacturer and the purchaser.

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